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EXAMINER

GOON, SCARLETT Y

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/517,692 | Applicant(s) EROMA ET AL. | |
| | Examiner SCARLETT GOON | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-74 is/are rejected.
- 7) ☒ Claim(s) 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicants' Amendment and Remarks filed on 4 August 2008 in which claims 1-37 were cancelled, and new claims 38-74 are added.

Applicants indicate that no new subject matter has been added by way of the amendments. Specifically, Applicants indicate that new claim 38 is a combination of original claims 1, 2, 6, 7 and 17; new claims 39 and 40 are based on new claim 38 and subject matter found in the specification; new claims 41-44 are based on original claims 3 and 4; new claims 45 and 46 are based on original claim 5; new claim 47 is based on original claim 4; new claims 48 to 56 are based on original claims 8 to 16; new claims 57 to 61 are based on original claims 18 to 22; new claims 62 and 63 are based on original claim 23; new claims 64 and 65 are based on original claims 24 and 25; new claims 66 and 67 are based on original claim 26; new claim 68 is based on original claims 27 and 28; new claims 69 to 73 are based on original claims 29 to 32; and new claim 74 corresponds to original claim 37. The Examiner confirms that no new matter has been added as a consequence of the amendments.

Claims 38-74 are currently pending and are examined on the merits herein.

Priority

This application is a National Stage entry of PCT/FI03/00533 filed on 2 July 2003 and claims priority to foreign application Finland 20021312 filed on 3 July 2002. A certified copy of the foreign priority document in Finnish is received.

Objections Withdrawn

In view of the cancellation of claim 5, all objections made with respect to claim 5 in the previous Office Action are withdrawn.

This objection has been **withdrawn**.

Rejections Withdrawn

In view of the cancellation of claims 1-37, all rejections made with respect to claims 1-37 in the previous Office Action are withdrawn.

These rejections have been **withdrawn**.

The following are new ground(s) or modified rejections necessitated by Applicants' amendment, filed on 4 August 2008, wherein the limitations in pending claims 38-40, 57 and 58 as amended now are different from their correspondingly canceled claims; claims 41-56 depend from claim 38, and claims 59-73 depend from claim 58. The limitations in the new claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, dated 5 February 2008, have been modified and are listed below.

Claim Objections

Claim 48 is objected to because of the following informalities: A claim should begin with a capital letter and end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-60 and 62-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIPO publication WO 91/07100 to Oravainen *et al.* (IDS dated 11 February 2005) and U.S. Patent No. 6,764,706 B1 to Heikkilä *et al.* (herein referred to as the '706 patent, of record), in view of US Patent No. 5,017,400 to Olinger *et al.* (herein referred to as the '400 patent, of record).

Oravainen *et al.* teach methods for the manufacture of a sweetener of a hard candy that consists of 30% - 70% by weight of xylitol and 70% - 30% by weight of sorbitol, maltitol, isomalt, lactitol, or a mixture thereof. The sugar alcohols used as a sweetener all have cariostatic properties (p. 1, line 32 - p. 2, line 2). One of the methods for the manufacture of a sweetener is described as the biocomponent crystallization technique where a basic composition is either xylitol/sorbitol or xylitol/lactitol, in a ratio of 40-65%/60-35% (p. 8, lines 33-35). In example 2 (p. 11), Oravainen *et al.* further teach a sweetener composition comprising xylitol, sorbitol and maltitol.

Oravainen *et al.* do not teach the limitations for the properties of the polyol composition as instantly claimed, nor does Oravainen *et al.* teach a process for the crystallization of the polyols as instantly claimed.

The Heikkilä '706 patent teaches a process for the crystallization of xylitol (claim 1), comprising the steps of (a) spraying an aqueous solution of xylitol, that is present at a concentration between 30% - 80% by weight, into contact with gas suspended fine solid particles containing microcrystalline xylitol, (b) causing substantial removal of the water solvent from said aqueous solution in the gas suspended state, and (c) causing said xylitol composition to be conditioned during a further drying step to provide a product consisting of microcrystals of xylitol agglomerated together in a random manner. In addition to microcrystalline xylitol, other sweeteners that are preferably non-cariogenic may be added to the xylitol composition (column 3, lines 40-45). The processed crystalline xylitol can be made into confectionery, foodstuffs, pharmaceuticals, and oral hygiene products (section 1, lines 6 and 35 and claim 18).

To obtain a solid feed of said fine solid particles containing microcrystalline xylitol, the Heikkilä '706 patent teaches that a portion of the microcrystalline xylitol particles, having a desired mean particle size below 0.2 mm (equivalent to 200 μm) are further recirculated (claim 17). In the absence of microcrystalline xylitol, the solid feed used at the start-up of the process may comprise milled crystalline xylitol from another source (column 2, line 62). Additionally, in example 3 of the reference, it is shown that powdered xylitol can also be used as the solid feed during start-up (column 8, line 57). The Heikkilä '706 patent further indicates that the suitable ratio of liquid xylitol feed to solid xylitol feed varies with the microcrystallization conditions (column 5, line 25), and can therefore be adjusted accordingly. Table 1 disclose conditions wherein the DS concentration of the feed solution 65.6% or 72% (columns 7 and 8). Additionally, the

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crystal mass may also include minor portions of amorphous xylitol (column 3, lines 22-23).

For the process involving water solvent removal, the Heikkilä '706 patent further stipulates that the process provides a xylitol material dried to a free moisture content of about 0.1% – 3% while said xylitol material is still in a suspended state (claim 6). Furthermore, the solid particles are to be retained in a fluidized state until they have grown to a predetermined weight (claim 16). The xylitol material is then collected by allowing it to settle on a moving belt and to form thereon a substantially continuous agglomerated porous powder layer (claim 8).

For the conditioning step in the process for crystallization of xylitol, the Heikkilä '706 patent indicates that the microcrystallized particles are conditioned at a temperature of about 50 °C - 100 °C (claim 9). Thereafter, the microcrystalline xylitol particles are broken up and further fractionated (equivalent to sieving) so as to provide particles having a mean particle size of about 0.1 – 10 mm (claims 12-14), preferably about 0.15 – 0.4 mm (column 6, line 23). However, the reference teaches that xylitol particle size is not critical, and may be varied according to intended use of the product (column 3, line 12).

The Heikkilä '706 patent also teaches that microcrystalline xylitol may be microcrystallized with other compounds (column 3, line 63). If the solid and/or liquid feed comprises other components, the product discharged from the microcrystallization apparatus will contain said other component(s) (column 3, line 65). These components can be an excipient, an active ingredient, and/or other sweetener (claim 3). An

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alternate process by which other components can be microcrystallized with xylitol is by using a secondary spray containing the excipient, active ingredient, or sweetener (column 4, line 1 and claim 4).

The Olinger '400 patent teaches a sweetener composition which contains, as its principal ingredients, from about 10% - 90% by weight of crystalline maltitol and from about 90% - 10% by weight of crystalline xylitol. Xylitol is the sweetest sugar-free alcohol and is considered isosweet to sucrose (column 1, line 38). Maltitol has a sweetness similar to that of sucrose, a sweetness equivalent to 0.8-0.9 of sucrose (column 2, line 8). Their comparable sweetness to sucrose makes these polyols ideal as sucrose replacements. The maltitol/xylitol sweetener composition is used to sweeten sugar-free products such as chocolate and other confectionery products, as well as dietetic products (column 1, line 9). Olinger *et al.* also teaches that this sweetener composition is noncariogenic and, in some instances, cariostatic (column 1, line 12).

With regards to claims 51-53 wherein the composition comprises an inner core portion comprising milled maltitol, xylitol and/or lactitol, it is noted that the references do not explicitly teach this limitation. However, as the Heikkilä '706 patent teaches that the solid feed used at the start up of the process may comprise milled crystalline xylitol in the absence of microcrystalline xylitol, one of ordinary skill in the art would conclude that the inner core portion would necessarily comprise milled xylitol.

With regards to claims 55 and 56 wherein the composition melts at about 90 °C and a melting enthalpy of 118 J/g, or a melting enthalpy which is lower than the calculated value for combined crystalline xylitol and crystalline maltitol, it is noted that

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the references do not these limitations. However, these chemical properties are specific and intrinsic to each and every compound and composition. Therefore, as the composition disclosed in the combined references meets the limitations of the instant claims, it is the Office's position that the melting temperature and enthalpy have also thus been met. Additionally, as Applicants indicate (section 0071), an equimolar mixture of maltitol and xylitol (1:1 ratio) forms an eutectic mixture having a melting point different from that of the individual polyols, and also, the composition has a lower melting enthalpy than the calculated value for a combination of crystalline xylitol and crystalline maltitol. Therefore, the requirement for a eutectic mixture and a specified enthalpy would be attained when the optimal ratio of 1:1 has been achieved.

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Oravainen *et al.*, regarding the use of three polyols in a sweetener composition, with the teachings of the Heikkilä '706 patent, concerning the process for the microcrystallization of xylitol, with the teachings of Olinger *et al.*, which teaches a sweetener composition that contains a combination of maltitol and xylitol. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Olinger *et al.*, that a combination of xylitol and maltitol exhibits sweetness synergism, and also lacks the undesired burning taste of pure xylitol. Moreover, it would have been *prima facie* obvious for one of ordinary skill in the art to vary the different conditions so as to obtain an optimal product and method of producing such a product. See below for recitation of a section from MPEP § 2144.05 regarding the obviousness of optimization of ranges.

The following is a quotation of MPEP § 2144.05:

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 4 August 2008 with respect to the rejection of claim 16 made under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,764,706 B1 to Heikkilä *et al.*, in view of U.S. Patent No. 5,017,400 to Olinger *et al.*, in view of WIPO publication WO 91/07100 to Oravainen *et al.*, have been fully considered but they are not persuasive.

Applicants argue that at the time of the present invention, it was very difficult to crystallize the polyols if they were not "pure". The Applicants further argue that the Heikkilä '706 patent teaches that the purity of the xylitol should be more than 80%, and therefore teaches away from the present invention. Furthermore, the Heikkilä '706 patent does not suggest or give any teaching towards a composition containing other

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polyols crystallized together with xylitol. This argument is not persuasive because difficulty in crystallizing the polyols does not render an invention non-obvious over the teachings of the prior art. Furthermore, Applicants argument that the Heikkilä '706 patent teaches that "the purity of xylitol should be more than 80%" is inaccurate. According to the citation indicated by Applicants, the Heikkilä '706 patent teaches that the xylitol purity of the product is preferably more than 80% indicating that it can be lower than 80%. With regards to the argument that the Heikkilä '706 patent does not suggest of give any teaching towards a composition containing other polyols crystallized together with xylitol, the Heikkilä '706 patent specifically teaches that other non-cariogenic sweeteners can be added to the microcrystalline xylitol (column 3, lines 44-45). As indicated above, maltitol, xylitol and sorbitol are non-cariogenic sweeteners.

New grounds of rejection for the currently amended claims, necessitated by Applicant's amendments, are as indicated above.

The rejection is still deemed proper and therefore adhered to.

Applicant's arguments filed 4 August 2008 with respect to the rejection of claims 13-16 made under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,764,706 B1 to Heikkilä *et al.*, in view of U.S. Patent No. 5,017,400 to Olinger *et al.*, in view of U.S. Patent No. 5,580,601 to Ribadeau-Dumas *et al.*, have been fully considered but they are not persuasive.

Applicants argue that the ribadeau-Dumas '601 patent does not overcome the deficiencies of the Heikkilä '706 patent and the Olinger '400 patent and thus should be withdrawn. The arguments to these deficiencies were as addressed above.

The rejection is still deemed proper and therefore adhered to.

Section [0002]

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over WIPO publication WO 91/07100 to Oravainen *et al.* (IDS dated 11 February 2005) and U.S. Patent No. 6,764,706 B1 to Heikkilä *et al.* (herein referred to as the '706 patent, of record), in view of US Patent No. 5,017,400 to Olinger *et al.* (herein referred to as the '400 patent, of record) as applied to claims 38-60 and 62-74 above, further in view of US Patent No. 6,821,535 to Nurmi *et al.* (herein referred to as the '535 patent, of record).

The teachings of Oravainen *et al.*, the Heikkilä '706 patent and the Olinger '400 patent were as disclosed above.

Oravainen *et al.*, the Heikkilä '706 patent and the Olinger '400 patent do not explicitly teach a process for the microcrystallization of a polyol wherein said polyol is sprayed intermittently onto dry feed particles.

The Nurmi '535 patent teaches a process for the production of chewable coated cores by hard panning of chewable cores in a coating pan or drum. This process makes the coating process quicker and more efficient (column 4, lines 16-19). Syrup containing crystallizable polyol(s) and/or sugar(s) is intermittently sprayed over a

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rotating bed of the cores and the cores are dried between sprayings with a flow of air (Abstract and claim 1). Two kinds of syrup are generally used in the coating procedure (column 7, lines 15-16). The first syrup is typically used until an increase to a desired pellet weight is achieved, then the second syrup is used to build up the remainder of the coat (column 7, lines 23-27). Nurmi *et al.* teaches that the syrup coatings may contain other additives such as flavors, pigments, special sweeteners and active ingredients (column 7, lines 38-42). Furthermore, the coatings can be applied by spraying solutions containing other (besides and in addition to xylitol) dissolved and/or suspended polyols, especially sweeteners such as lactitol, maltitol, mannitol, isomalt and sorbitol (column 7, lines 49-53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Oravainen *et al.*, regarding the use of three polyols in a sweetener composition, with the teachings of the Heikkilä '706 patent, concerning the process for the microcrystallization of xylitol, with the teachings of Olinger *et al.*, which teaches a sweetener composition that contains a combination of maltitol and xylitol, with the teachings of the Nurmi '535 patent, regarding a method of producing chewable coated cores by intermittent spray. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Olinger *et al.*, that a combination of xylitol and maltitol exhibits sweetness synergism, and also lacks the undesired burning taste of pure xylitol. Moreover, it would have been *prima facie* obvious for one of ordinary skill in the art to combine the

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different methods and compositions of the disclosed references to obtain an optimal composition and method of preparing such a composition.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 4 August 2008 with respect to the rejection of claims 11, 12 and 22 made under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,764,706 B1 to Heikkilä *et al.*, in view of U.S. Patent No. 5,017,400 to Olinger *et al.*, in view of U.S. Patent No. 6,821,535 to Nurmi *et al.*, have been fully considered but they are not persuasive.

Applicants argue that the Nurmi '535 patent does not overcome the deficiencies of the Heikkilä '706 patent and the Olinger '400 patent and thus should be withdrawn. The arguments to these deficiencies were as addressed above in section [0001].

The rejection is still deemed proper and therefore adhered to.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623